K010551

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510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness for the EBI DynaFix® VS™ Osteotomy System is provided as required per Section 513(I)(3) of the Food, Drug and Cosmetic Act.

1. **Sponsor:**
EBI, L.P.
100 Interpace Parkway
Parsippany, NJ 07054

Contact Person: Patricia Flood, RAC
Telephone: (973) 299-9022, ext.3318

Date Prepared: February 23, 2001

2. **Proprietary Name:** EBI DynaFix® VS™ Osteotomy System

Common Name: Bone Plate and Accessories

Classification Name: Single/Multiple Component Metallic Bone Fixation Appliances and Accessories, 21 CFR 888.3030.

3. **Predicate or Legally Marketed Devices:**

- Arthrex Opening Wedge Osteotomy System (K973812)

4. **Description of Device:**

The System consists of an osteotomy plate and bone screws.

5. **Intended Use:**

The EBI DynaFix® VS™ Osteotomy System is intended for fixation following acute corrective osteotomies.

6. **Materials:**

The components of the System are manufactured from titanium alloy (Ti-6Al-4V) per ASTM F136.

7. Comparison of the technological characteristics of the device to predicate devices:

There are no significant differences between the EBI DynaFix® VS™ Osteotomy System and the Arthrex Opening Wedge Osteotomy System. The EBI DynaFix® VS™ Osteotomy System is substantially equivalent* to the predicate device in regards to intended use, material, and function. The mechanical testing results demonstrate that the device complies with applicable standards and meets all of its functional requirements.

*Any statement made in conjunction with this submission regarding a determination of substantial equivalence to any other product is intended only to relate to whether the product can be lawfully marketed without pre-market approval or reclassification and is not intended to be interpreted as an admission or any other type of evidence in patent infringement litigation. [Establishment Registration and Premarket Notification Procedures, Final Regulation, Preamble, August 23, 1977, FR 42520 (Docket No. 76N-0355.)]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 17 2001

Ms. Patricia Flood
Senior Regulatory Affairs Specialist
EBI, L.P.
100 Interpace Parkway
Parsippany, New Jersey 07054

Re: K010551
Trade Name: EBI Dynafix VS™ Osteotomy System
Regulation Number: 888.3030
Regulatory Class: II
Product Code: NDF and NDH
Dated: February 23, 2001
Received: February 26, 2001

Dear Ms. Flood:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K010551

Device Name: EBI DynaFix® VS™ Osteotomy System

Indications For Use:

The EBI DynaFix® VS™ Osteotomy System is intended for fixation following acute corrective opening wedge osteotomies in long bone.

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010551

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X (Per 21 CFR 801.109) OR Over-The-Counter Use (Optional Format 1-2-96)